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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/502,176	02/10/2000	Steven Piric-Shepherd	05940-0141	4843

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 01/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/502,176

Applicant(s)

PIRIE-SHEPHERD ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-12,15,16 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 27 is/are allowed.
- 6) ☒ Claim(s) 1-4,6-12, 15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>20</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 24, 2002 has been entered.

2. Claims 1-4, 6-13, 15, 16 and 27 are pending.

Claims 1, 6 and 7 have been amended.

Claims 1-4, 6-12, 15, 16 and 27 are examined on the merits.

Specification

3. The disclosure is no longer objected. Applicants supplied a substitute specification correcting several errors.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

4. The rejection of claims 1-4, 6-12, 15 and 16 under 35 U.S.C. 112, second paragraph, in Paper number 15 (page 4, paragraph 11) as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

New Grounds of Rejection and Maintained Rejections

Claim Rejections - 35 USC § 112

5. Claims 1-4, 6-12, 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 1 is vague and indefinite in the recitation "a protein corresponding to". It is not clear if the corresponding protein is similar or equivalent to the deglycosylated kringle 1-3 fragment of the plasminogen protein. Accordingly, the metes and bounds of the claim cannot be determined.

Claim Rejections - 35 USC § 102

6. The rejection of claims 1-4, 6, 8, 9 and 12 under 35 U.S.C. 102(b) as being anticipated Sim et al. (Cancer Research 57:1329-1334, April 1, 1997) is maintained.

Applicants aver with the amendment of claim 1, which incorporates the recitation "a protein corresponding to" that the instant rejection has been overcome. This argument is not persuasive.

The language added to claim 1 does not preclude the anticipatory Sim reference. As set forth in Paper number 11 (mailed September 7, 2001) and Paper number 15 (mailed May 21, 2002) Sim does disclose Applicants' claimed invention. Sim discloses a composition comprising recombinant angiostatin (see page 1330, column 1, entire section of "Purification of Recombinant..."). Sim notes on page 1331, column 1, last full sentence "...recombinant Angiostatin protein consisting of the doublet was used in all *in*

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vitro and *in vivo* assays...", as pointed out by Applicants. The caption of Figure 2 on page 1331 provides information reflective of Sim purifying deglycosylated, as well as glycosylated recombinant Angiostatin (also see bridging paragraph of page 1331 and 1332, especially explanation of Figure 2). In view of the open language "composition comprising..." the claim reads on kringles 1-3, as well as additional kringles.

Furthermore, Sim digested the recombinant Angiostatin protein with endoglycosidase H and O-glycanase with prior neuraminidase treatment to remove carbohydrate moieties (see page 1331, column 2, bridging sentence and first two full sentences). Consistent with this enzyme treatment the deglycosylated fragment inherently lacked a bisialylated-biantennary glycan and a N-linked carbohydrate moiety with an amino acid substitution at an amino acid position corresponding to the N-glycosylation site of human plasminogen. Sim states in the abstract that the disclosed recombinant protein comprises kringles 1-4 of human plasminogen starting at amino acid residue 93, this is within the range of at approximately amino acid 87 of human plasminogen.

7. Claims 7, 10, 11, 15 and 16 are free of the art.

Allowable Subject Matter

8. Claim 27 is allowed.

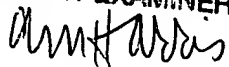
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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

ALANA HARRIS
PATENT EXAMINER



Alana M. Harris, Ph.D.
December 31, 2002